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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,117	12/29/2003	Derek O'Hagan	PP020038.0003	1746

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EXAMINER	
MINNIFIELD, NITA M	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/748,117	O'HAGAN, DEREK	
	Examiner	Art Unit	
	N. M. Minnifield	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-85* is/are pending in the application.

4a) Of the above claim(s) *2,17 and 29-85* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-16 and 18-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *2 17 29-85* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed December 23, 2008 is acknowledged and has been entered. Claims 1-85 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment to the claims and/or comments with the exception of those discussed below.

2. Claims 2, 17 and 29-85 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and/or species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 16, 2007.

3. Claims 1, 3-16 and 18-28 have been examined in the instant application.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1, 3-16, 18, 19 and 22-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Hagan et al (WO 98/33487) taken with Hawkins et al (6290973).

O'Hagan et al teaches poly(lactide) or poly(lactide-co-glycolide) microparticles with adsorbed antigens (abstract). O'Hagan et al teaches "Particulate carriers with adsorbed or entrapped antigens have been used in an attempt to elicit adequate immune responses. Such carriers present multiple copies of a selected antigen to the immune system and promote trapping and retention of antigens in local lymph nodes. The particles can be phagocytosed by macrophages and can enhance antigen presentation through cytokine release. Examples of particulate carriers include those derived from polymethyl methacrylate polymers, as well as microparticles derived from poly(lactides) and poly(lactide-co-glycolides), known as PLG." (pp. 2-3; see also p. 7) O'Hagan et al teaches the use of microparticles with adsorbed antigens provides a safe and effective approach for enhancing the immunogenicity of a wide variety of antigens (p. 5). O'Hagan et al teaches that the microparticle has a diameter of about 100 nm to about 150 μm, more preferably about 200 nm to about 30 μm and most preferably about 500 nm to about 10 μm (p. 6). O'Hagan et al teaches the claimed immunogenic composition except for a synthetic phospholipid.

However, Hawkins et al teaches novel compounds that function as immunological adjuvants when co-administered with antigens (abstract; column 2, lines 10-13). Hawkins et al teaches the use of various synthetic phospholipids that can be used in vaccine compositions, pharmaceutical compositions or immunostimulatory compositions (cols. 3-7; cols. 187-188: ER804053, ER804057). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine the teachings of O'Hagan et al with Hawkins et al to make an immunogenic composition comprising water, polymer microparticle, antigen adsorbed to microparticle and synthetic phospholipids (various phospholipids) for the purpose of immunizing a subject to increase or enhance immunogenic activity, immune response or stimulate/enhance protection against an infectious antigen for example. The claimed invention is prima facie obvious in view of the combined teachings of the prior art, absent any convincing evidence to the contrary.

The rejection is maintained for the reasons of record. Applicant's arguments filed December 23, 2008 have been fully considered but they are not persuasive. Applicants have asserted that the Examiner "Rather than providing "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness" as required by *KSR, the* Examiner has instead taken multiple references disclosing various elements of the claimed invention and combined them together as an obviousness rejection. Moreover, overlooked in the Examiner's analysis is the fact that there must be a reasonable expectation of success. See MPEP 2143.02 and the cases cited therein. Where immunological adjuvants are concerned, however, one of ordinary skill in the art would not have

a reasonable expectation of success. In this regard, see, for example, the attached article from R. Edelman, *Molecular Biotechnology,* 21(2) 2002, pp.129-148 (Edelman), which demonstrates that those of ordinary skill in the art would have recognized that (a) every adjuvant (including microparticle adjuvants) has a complex and often multi-factorial immunological mechanism, usually poorly understood in vivo, (b) many determinants of adjuvanticity exist and (c) each adjuvanted vaccine is unique. Accordingly, the choice of an adjuvant frequently depends upon experimental trial and error, *ld.* In view of the foregoing, it is respectfully submitted that, without undue hindsight gained upon review of the present specification and claims, the presently pending claims are unobvious in view of the teachings of Levy and Weiner. See, e.g., MPEP 2142.. second paragraph, *Akzo N.V. v. U.S. International Trade Commission,* 808 F.2d 1241, 1480-81, 1 U.S.P.Q.2d, 1241, 1246 (Fed. Cir. 1986), *cert. denied,* 482 U.S. 909 (1987), and *Loctite Corp. v. Ultraseal Ltd.,* 781 F.2d 861, 874, 228 U.S.P.Q. 90-99 (Fed. Cir. 1985). Nor would not be a reasonable expectation of success. Consequently, *a prima facie* case of obviousness has not been established by the Examiner. For at least these reasons, reconsideration and withdrawal of the Examiner's rejection are requested." (see Remarks, pp. 17-18).

First, it is noted that the 103 rejection is made over O'Hagan and Hawkins, not the teachings of Levy and Weiner.

The claimed invention is directed to a composition, which the combined references of O'Hagan taken with Hawkins teach. Both references teach components of the claimed invention for the same purpose, an adjuvant (see above). Therefore, it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a

third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.). See also In re Crockett, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and Ex parte Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held prima facie obvious).

Although, Applicants have referenced Edelman et al, this reference is not a part of the 103 obviousness rejection and Applicants have not set forth the specific deficiencies of the teachings of the combination of references of O'Hagan taken with Hawkins. It is true that Edleman says there are problems with developing adjuvants. However, at the time of the invention, O'Hagan teaches that "adsorbing selected viral antigens to microparticles derived from a poly(α-hydroxy acid), provides for superior immune responses. Accordingly, then, the invention is primarily directed to methods and compositions which include such micro-particles, as well as to processes for producing the same. The use of microparticles with adsorbed antigens provides a safe and effective approach for enhancing the immunogenicity of a wide variety of antigens. Accordingly, in one embodiment, the invention is directed to a composition comprising a selected viral antigen adsorbed to a poly(α-hydroxy acid) microparticle and a pharmaceutically

acceptable excipient. In an additional embodiment, the invention is directed to a method of immunization which comprises administering to a vertebrate subject a therapeutically effective amount of the microparticle composition above. In yet an additional embodiment, the invention is directed to a method for eliciting a cellular immune response in a vertebrate subject comprising administering to a vertebrate subject a therapeutically effective amount of a selected viral antigen adsorbed to a poly(α-hydroxy acid) microparticle." (pp. 4-6) And Hawkins teaches novel compounds (i.e. phospholipids)that function as immunological adjuvants. Therefore, it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.). See also In re Crockett, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and Ex parte Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held prima facie obvious).

The Supreme Court further stated that: When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can

implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. Id. at ___, 82 USPQ2d at 1396. When considering obviousness of a combination of known elements, the operative question is thus "whether the improvement is more than the predictable use of prior art elements according to their established functions." Id . at ___, 82 USPQ2d at 1396.

In the instant case both O'Hagan and Hawkins teach the need for new adjuvants to help in improved immunogenicity of antigens and an improved immune response in a subject. They both teach a finite number of identified, predictable solutions, all with a reasonable expectation of success. O'Hagan et al teaches the use of microparticles with adsorbed antigens provides a safe and effective approach for enhancing the immunogenicity of a wide variety of antigens (p. 5). Hawkins et al teaches novel compounds that function as immunological adjuvants when co-administered with antigens (abstract; column 2, lines 10-13). Hawkins et al teaches the use of various synthetic phospholipids that can be used in vaccine compositions, pharmaceutical compositions or immunostimulatory compositions (cols. 3-7; cols. 187-188: ER804053, ER804057).

The claimed invention is prima facie obvious in view of the teachings of O'Hagan and Hawkins absent any convincing evidence to the contrary.

7. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Hagan et al (WO 98/33487) taken with Hawkins et al (6290973) as applied to claims 1, 3-16,18, 19 and 22-28 above, and further in view of Muttilainen

(Microbial Pathogenesis, 1995, 18:423-436) and Cox et al (Vaccine, 1997, 15/3:248-256).

O'Hagan et al and Hawkins et al have been described supra. O'Hagan et al and Hawkins et al teach the claimed invention except for the specific antigen, *Neisseria meningitidis* and meningitis B. However, Muttilainen et al teaches a composition comprising meningitis B antigen, the P1 protein, in a phospholipid vesicles or liposomes (abstract, methods and materials). Muttilainen et al teaches the liposome formulation (P1 protein and liposomes) is good as an adjuvant (p. 432). Cox et al teaches that the "purpose of adjuvant combinations is to combine various adjuvant components to achieve the desired mix of immunological responses. The best-known adjuvant combination is Freund's complete adjuvant (FCA) which combines the immunomodulatory properties of ***Mycobacterium tuberculosis*** (essentially TDM and MDP) along with the short-term depot effect of w/o emulsions, This adjuvant generates very strong Thl and Th2 responses and is especially suited to hydrophilic immunogens. The Ciba-Geigy adjuvant formulation is a modification of FCA which uses a metabolizable oil (squalene) and nor-MDP. It has been used successfully in clinical trial. Despite the success of w/o formulations as a basis for adjuvant combinations (especially FCA and TiterMax) they do not normally induce CTL responses and require multiple doses for effective immunization i.e. long-term depots are not established." (p. 253) Cox et al teaches that "[L]iposomes offer a versatile formulation into which various immunomodulatory molecules can be incorporated. Examples include MPL, lipophilic MDP and Quil A. Although hydrophilic molecules can be incorporated within a liposome, the efficiency is generally low and liposome formulations are most suited for amphipathic immunogens. One other interesting

combination is the mixture of MPL and QS21. Selection of the "best" adjuvant combination requires some knowledge of the chemical nature of the protective immunogen(s) and some idea of the nature of the immune response which is likely to be protective. However, even where knowledge of both these issues is minimal, rational selection of a small number of basic formulations and additives should permit selection of an effective adjuvant system. It is hoped that this review will help in this rational selection." (p. 253)

Barring any unexpected results and/or convincing evidence to the contrary, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine the teachings of O'Hagan et al, taken with Hawkins et al, further in view of Muttilainen et al and Cox et al with a reasonable expectation of success to prepare the immunogenic composition as instantly claimed. Cox et al teaches that using a combination of adjuvants is desirable to achieve a mix of immunological responses.

Additionally, *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007), discloses that if a technique has been used to improve one method , and a person of ordinary skill would recognize that it would be used in similar methods in the same way, using the technique is obvious unless its application is beyond that person's skill. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) also discloses that "The combination of familiar element according to known methods is likely to be obvious when it does no more than yield predictable results". It well known in the art to use combinations of adjuvants, which adjuvants are taught by Cox et al. Thus, it would be obvious to apply a known technique to a known product to be used in a known method that is ready for improvement to yield predictable results.

The rejection is maintained for the reasons of record. Applicant's arguments filed December 23, 2008 have been fully considered but they are not persuasive. Applicants' arguments regarding O'Hagan and Hawkins have been addressed above. Applicants have asserted that the present invention under examination is an immunogenic composition, not a method. It is noted that the combined references does teach the claimed immunogenic composition. Applicants have argued that KSR involved addressing a known problem with a finite number of identified, predictable solutions and that the art related to the claimed invention is unpredictable (see Edelman). Applicants have also asserted that there are a near-infinite number of solutions available to the ordinarily skilled artisan (e.g. Cox, which evidences a large number of solutions, even as of 1997)

It is noted that the Examiner does not agree with the assessment of Cox, It is noted that Cox teaches that "To this point we have considered a number of basic adjuvant formulations in terms of their modes of adjuvant action *(Table 1)*. In summary, immunomodulators influence both the magnitude of the immune response, the Thl/Th2 balance of that response and hence the isotype of antibody produced and the extent of DTH. Presentation is important when neutralizing antibody is a major requirement and may influence affinity and duration of the response. Adjuvants capable of cytosolic delivery are the best option if CTL responses are desired. Targeting increases the efficiency of delivery of antigen to APCs and becomes important when antigen cost is high. Short-term depots similarly increase efficiency whilst long-term depots offer the opportunity for single-dose multi-release vaccines. The purpose of adjuvant combinations is to combine various adjuvant components to achieve the desired mix of immunological responses. The best-known adjuvant combination is Freund's

complete adjuvant (FCA) which combines the immunomodulatory properties of *Mycobacterium tuberculosis* (essentially TDM and MDP) along with the short-term depot effect of w/o emulsions. This adjuvant generates very strong Thl and Th2 responses and is especially suited to hydrophilic immunogens. The Ciba-Geigy adjuvant formulation is a modification of FCA which uses a metabolizable oil (squalene) and nor-MDP. It has been used successfully in clinical trial. Despite the success of w/o formulations as a basis for adjuvant combinations (especially FCA and TiterMax) they do not normally induce CTL responses and require multiple doses for effective immunization i.e. long-term depots are not established. Many combined adjuvants based on o/w emulsions have been described. The best known are the Syntex adjuvant formulation (SAF) which contains the non-ionic block copolymer Ll21 and threonyl MDP; the Ribi DETOX adjuvant which contains MPL and CWS (cell wall skeleton) and the Chiron MF59 adjuvant which contains MTP-PE (muramyl tripeptide-phosphatidyl ethanolamine), a lipophilic MDP derivative. These adjuvant formulations are of major value for amphipathic immunogens; for hydrophilic immunogens, the o/w component of the formulation will confer minimal benefits, and a w/o based formulation would be preferable. Liposomes offer a versatile formulation into which various immunomodulatory molecules can be incorporated. Examples include MPL, lipophilic MDP and Quil A. Although hydrophilic molecules can be incorporated within a liposome, the efficiency is generally low and liposome formulations are most suited for amphipathic immunogens. One other interesting combination is the mixture of MPL and QS21. Selection of the "best" adjuvant combination requires some knowledge of the chemical nature of the protective immunogen(s) and some idea of the nature of the immune response which is likely to be protective. However,

even where knowledge of both these issues is minimal, rational selection of a small number of basic formulations and additives should permit selection of an effective adjuvant system. It is hoped that this review will help in this rational selection." (p. 253)

Muttilainen teaches a composition comprising meningitidis serogroup B P1 antigen in phospholipid vesicles or liposomes and that the liposome formulation is good as an adjuvant and that Cox teaches that using a combination of adjuvants is desirable to achieve a mix of immunological responses (see above).

Applicants have asserted that the Examiner "rather than providing "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness" as required by *KSR, the* Examiner has instead, "with the benefit of undue hindsight, taken random references disclosing various elements of the claimed invention and combined them together as an obviousness rejection. The Examiner has further created reasons for the claimed combination (i.e., that Cox teaches that using a combination of adjuvants is desirable to achieve a mix of immunological responses) that are simply not supported by adjuvant science. First, as indicated above, adjuvant selection and combination is a complex and poorly understood undertaking. Moreover, in various instances, a combination of adjuvants is not dictated. One example of this is the *N. meningitidis* serogroup B vaccine from Novartis Vaccine and Diagnostics Inc., which is comprised five proteins with an alum adjuvant. Thus, contrary to the Examiner's assertion that one of ordinary skill in the art would be motivated to combine multiple adjuvants together, this real world example demonstrates that there is no problem to be solved at all, because alum is by itself sufficient. Finally, the Examiner has ignored the requirement that one of ordinary skill in the art must have a reasonable

expectation of success. Such an expectation is unfound here, for example, due to the complex and poorly understood nature of adjuvant action. For at least these reason, it is respectfully submitted that claims 20 and 21 are patentable over O'Hagan, Hawkins, Muttilainen and Cox." (see Remarks p. 19-20).

However, it is the Examiner's position that the combined teachings of the prior art teaches the instantly claimed immunogenic composition. As previously stated Cox provides motivation and suggestion for using multiple adjuvants (see above). O'Hagan, Hawkins, Muttilainen and Cox teach the components of the claimed invention for the same purpose, an adjuvant and immunogenic composition (see above). Therefore, it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.). See also In re Crockett, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and Ex parte Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held prima facie obvious).

The Supreme Court further stated that: When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it,

either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. Id. at ___, 82 USPQ2d at 1396. When considering obviousness of a combination of known elements, the operative question is thus "whether the improvement is more than the predictable use of prior art elements according to their established functions." Id . at ___, 82 USPQ2d at 1396.

As set forth above, the combination of references teaches combining prior art elements according to known methods to yield predictable results. In the instant case, O'Hagan, Hawkins, Muttilainen and Cox teach the need for new adjuvants to help in improved immunogenicity of antigens and an improved immune response in a subject. They teach a finite number of identified, predictable solutions, all with a reasonable expectation of success.

8. No claims are allowed.

9. No claims are allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the

advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert B. Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. M. Minnifield/
Primary Examiner, Art Unit 1645
March 16, 2009